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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/227,742 | Applicant(s) BLOOM ET AL. | |
| | Examiner Yucel Remy | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 45-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input checked="" type="checkbox"/> Other: <i>detailed action</i> |

DETAILED ACTION

Claims 45-71 are pending in the application. This Office action is in response to the amendment filed 16 March 2001.

Continued Prosecution Application

The request filed on 16 March 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09227,742 is acceptable and a CPA has been established. An action on the CPA follows.

Oath/Declaration

Applicants' desire to hold the matter of the Oath/Declaration in abeyance is noted; however, the present Oath/Declaration remains defective for the reasons first made of record in the Office action mailed 12 April 1999, paper 2.

Response to Amendment

Claims 45-71 stand rejected under the judicially created doctrine of obviousness-type double patenting for the reasons made of record in the Office actions mailed 22 September 1999 and 05 June 2000. Applicants' willingness to file a Terminal Disclaimer (page 4, amendment filed 05 December 2000 is noted; however, the rejection is maintained in absence of said disclaimer.

The rejection of claims 45-49, 51-56, 70 and 71 under 35 U.S.C. 102(b) as being anticipated by Inoue et al. has been withdrawn in light of Applicants' amendments.

Claims 45-53, 58-65, 70 and 71 stand rejected under 35 U.S.C. 112, first paragraph, scope of enablement for the reasons made of record in the Office actions mailed 22 September 1999 and 05 June 2000 and for the reasons presented below.

Claims 45-57 stand rejected under 35 U.S.C. 35 U.S.C. 112, first paragraph (new matter) for the reasons set forth below.

Claims 58-69 stand rejected under 35 U.S.C. 102(b) as being anticipated by de Mendoza II (JBC, 1983) for the reasons essentially set forth in previous Office actions and further set forth below.

Claims 58, 59, 63-67, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al.

Response to Arguments

At page 9 of the remarks filed 05 December 2000, Applicants refer to pages 13-20 of the remarks submitted 21 March 2000 as providing a detailed rebuttal to the scope of enablement rejection for claims 45-69. Applicants still contend that the Examiner has not met the burden of establishing a *prima facie* case of non-enablement. Applicants' position is that the Examiner has only provided allegedly conclusory reasons for the non-enablement thereby rendering the rejection improper. None of these arguments new and remain unconvincing.

The rejection of record presents a detailed analysis of the Forman factors which speak directly to the unpredictable nature of the claimed invention. Surely Applicants need not be reminded that the scope of the claims must be commensurate with the scope of the teachings of their specification, "the specification must teach those skilled in the art how to make and use the

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full scope of the claimed invention without undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed.Cir. 1993). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971).

As set forth previously, this is simply not the case. Applicants disclosure teaches that increases in unsaturated fatty acids result in increased viability and transformation ability. Applicants' specification is completely silent with respect to what happens with increases in saturated fatty acids or increases in total fatty acids with no change in the ratio between saturated and unsaturated fatty acids. The basis of the rejection is not whether the skilled artisan would know how to make changes in fatty acid content, but rather, would the skilled artisan know the ramifications or results of increasing saturated or total fatty acid content without undue experimentation? Because Applicants specification does not teach how increases in unsaturated fatty acids contribute to increased viability and transformation ability, the skilled artisan would not be able to ascertain the effect of increased total fatty acids or saturated fatty acids without trial and error, empirical experimentation which is undue. Indeed the art made of record, (i.e. de Mendoza, Emtseva, and previously Kole or Tsien) all teach that bacteria (E. coli among others) display increased viability as a result of increases in the unsaturated fatty acid content of their membranes (it is also noted that Applicants refer to these references at 20 of the remarks filed 21 March 2000). Therefore, it is not at all apparent or predictable what would happen with increases only in saturated fatty acids, for example. Because the prior art does not provide the guidance needed to practice the full scope of the invention, this must be provided by Applicants'

specification, which, as previously discussed (both above and in past Office actions), also fails to provide said guidance. In the absence of these teachings, the specification cannot enable the full scope of the present claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 45-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 45 and 46 have been amended to recite the proviso "wherein said increasing the fatty acid content is not accomplished by growing said bacterium (or bacteria, for claim 46) at a reduced temperature, relative to the temperature at which a bacterium is grown in which the fatty acid content is not increased."

The specification does not appear to provide support for this proviso. It is further noted that Applicants fail to indicate those portions of the specification which support this amendment (see section II of the Remarks, filed 08 December 2000). Applicants are reminded that any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion.

Absent this basis, the amendment represents new matter and must be canceled.

Claims 45-53, 58-65, 70 and 71 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods in which the unsaturated fatty acids are increased via introduction of nucleic acid sequences which encode one or more products which increase unsaturated fatty acid content of membranes, does not reasonably provide enablement for any other methods of increasing unsaturated fatty acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The Office actions of mailed 22 September 1999 and 05 June 2000 set discussed in detail the issue of increasing unsaturated fatty acids. In addition to this issue, it appears that the specification fails to enable methods other than the introduction of nucleic acids into the bacteria in order to effect an increase in (unsaturated) fatty acid content. Applicants' specification lacks essential material (that which is necessary to provide an enabling disclosure of the claimed invention--see MPEP608.01 (p)). As such the claims stand rejected under 35 U.S.C. 35 U.S.C. 112, first paragraph, scope of enablement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 58-69 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by de

Mendoza II (TIBS, 1983).

The teachings of de Mendoza II have been presented previously (papers 2, 7 and 12, mailed 12 April 1999, 22 September 1999 and 05 June 2000, respectively). As stated in previous Office actions, de Mendoza et al. teach that normal cell function requires membranes that are largely fluid and that in response to lower temperatures, the membranes undergo a reversible change of state from fluid, fluid-like state to a hexagonally ordered array of the fatty acid chains (becoming "solid" or more rigid). They teach that bacteria regulate their lipid phase transition in response to temperature to ensure fluid fluid-like membranes for normal cell function and do so by regulating the amount of unsaturated fatty acids in their membranes (order-disorder transition). They teach that by developing a regulatory mechanism based on β -ketoacyl-ACP synthase II, bacteria (for example *Escherichia*) are able to lower the temperature of the order-disorder lipid phase transition to optimize membrane function at lower temperatures (such as those recited in the instant claims). The bacteria do so by increasing the synthesis of *cis*-vaccenic acid and thus increase the amount of said unsaturated fatty acid in their membranes.

They also describe experiments in which the copy number for *fabB* is increased in a *fabF1* strain. In these cells the increase in *cis*-vaccenic acid synthesis is not temperature dependent, but results in increased levels of the unsaturated fatty acid in the bacterial membrane.

By optimizing membrane function to ensure fluid, fluid-like membranes at lower temperatures, enhanced viability is therefore (inherently) achieved because these membranes are less susceptible to "fractionation" which occurs after freeze-thaw cycles (a known method by which bacteria are disrupted) than rigid membranes with higher levels of saturated fatty acids.

Applicants ignores the sound technical reasoning provided in the rejection which amply

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supports the proposition that the inherent characteristic flows from the teachings of the cited reference (see remarks at page 6). Clearly, that bacteria such as E. coli modify the fatty acid content of their membranes in response to lower temperatures to preserve proper membrane function directly speaks to increased viability. The viability of a bacterium is the single greatest factor in determining its transformation ability. Even one of less than ordinary skill in the art would immediately appreciate that dead cells do not have transformation ability.

Additionally, Applicants specification is written such that "viability" and "transformation ability" are used almost interchangeably or synonymously. While these terms may denote different facets of the invention, they go hand in hand and the conditions which favor one also favor the other. Therefore, teachings which illustrate one (viability) also illustrate the other (especially since viability is essential for transformation ability). Applicants have merely changed the preamble of the claims from "viability" to "transformation ability" while keeping the single method step the same, specifically, increasing fatty acid content. It appears that there is no other step(s) which are essential for obtaining increased transformation ability. Because the reference teaches the singly recited step of increasing fatty acid in the bacterial membrane, it anticipates the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Remy Yucel, Ph.D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday-Friday, 8:00am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Dianiece Jacobs whose telephone number is (703) 305-3388.



Remy Yucel, Ph.D.
Primary Examiner
Art Unit 1636

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June 4, 2001